

USSN: 09/939,098

DRAFT AMENDMENT

Docket No.: 687-401

A 2

[0054] Depending upon the parameters of the coating process used, varying degrees of silicone thickness surrounding the mesh yarns can be obtained. However, in preferred embodiments, the holes or pores 24 remain open after coating. Referring to Figures 2A, 2B, 3A and 3B, depending upon the desire or need of the user, a sling can be coated so as to comprise a coated mesh material having a thickness ranging from about .024 inches (0.61 mm) to about .036 inches (0.914 mm) (Figures 3A, 3B) or from about .020 inches (0.508 mm) to about .025 inches (0.635 mm) (Figures 2A and 2B). In one embodiment, the thickness of the sling material in the uncoated state is about .020 inches (0.508 mm) plus or minus about 0.002 inches. In a preferred embodiment, the size of the holes or pores 24 after coating is preferably in the range of about .040 inches (1.016 mm) to about .055 inches (1.397 mm).

Please replace paragraph [0056] with:

A 3

[0056] It is contemplated that the present invention can be used with a variety of sling systems and methods for treating urinary incontinence. For example, a coated sling in accordance with the present invention, can be used with the system for the long term cure of recurrent urinary female incontinence as described in co-pending U.S. Patent [application Serial] No. 6,328,686, the entire disclosure of which is hereby incorporated by reference. When used in such a system, a silicone-coated sling can be installed *in vivo* using the vaginal installation procedure as described in the application. Alternatively, a coated sling in accordance with the present invention can be prefabricated according to the dimensions and shapes as described, for example, in U.S. Patent No. 6,042,534 issued March 28, 2000 entitled "Stabilization sling for use in minimally invasive pelvic surgery" and installed as described in U.S. Patent No. 6,042,534. A coated sling of the present invention can also be installed abdominally or laparoscopically using procedures well known in the art.

Please replace paragraph [0071] with:

A 4

[0071] After removing the material from the hoops, the silicone coated mesh material can then be fabricated as desired into a sling for use in treating urinary incontinence. As

USSN: 09/939,098

DRAFT AMENDMENT

Docket No.: 687-401

A4
described previously, a silicone coated mesh material of the present invention, can be used to fabricate a sling such as described in U.S. Patent No. 6,328,686, and then surgically implanted into a patient suffering from urinary incontinence.

Please replace paragraph [0078] with:

A5
[0078] The invention as disclosed in the embodiment of Figures 7A and 7B is not limited to visual indicia in the form of geometrical patterns. For example, the visual indicia could be a series of seemingly random lines that, under the target tension, become aligned into a straight line or into a geometrical pattern such as a triangle. As another example, the visual indicia could be a collection of marks or characters that, under the target tension, become aligned to spell a word such as "OK," or "STOP," or "LIMIT." In one embodiment the word could spell the manufacturer of the sling, such as "AMS."

A version marked up to show changes made to the specification relative to the previous version of the specification is attached.

In the Claims:

Please amend the claims as follows:

1. (Amended) A sling for insertion into a patient comprising:
a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;
said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;
wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,
said first and second elongation property being different from each other, and
wherein said second elongation property is greater than said first elongation property.

Plcasc cancel claim 2.

USSN: 09/939,098

DRAFT AMENDMENT

Docket No.: 687-401

- A7
3. (Amended) A sling for insertion into a patient comprising:
a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;
said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;
wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,
said first and second elongation property being different from each other, and
wherein said first elongation property is approximately 8% elongation beyond a normal state of said sling material when said sling material is subjected to a tension of approximately 5 lbs.

- A8
5. (Amended) A sling for insertion into a patient comprising:
a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;
said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;
wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,
said first and second elongation property being different from each other, and
wherein said first elongation property is in the range of approximately 24%-28% elongation beyond a normal state of said sling material when said sling is subjected to a tension of approximately 20 lbs.

Please cancel claims 7-9 without prejudice.

- A9
10. (Amended) A sling for insertion into a patient comprising:
a surgical sling adapted to be implanted in a tension free rest position to support the urethra;

USSN: 09/939,098

DRAFT AMENDMENT

Docket No.: 687-401

49
said surgical sling material comprising a length of polypropylene material having pores for promoting tissue ingrowth, a pair of major surfaces, a pair of ends and a pair of edges, and a longitudinal axis;

wherein said polypropylene material has a central region with at least one major surface coated with silicone, the silicone coated central region being adapted to be placed adjacent the urethra to avoid tissue erosion, and end regions without silicone coating; and

wherein said silicone coated polypropylene in the central region has a thickness within the range of approximately .024" (0.61 mm) to .036" (0.914 mm).

Please cancel claim 11 without prejudice.

50
12. (Amended) A sling for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said first elongation property is in the range of approximately 19.5-21.5% elongation beyond a normal state of said sling material when said sling material is subject to a tension of approximately 20 lbs.

51
14. (Amended) A sling for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

USSN: 09/939,098

DRAFT AMENDMENT

Docket No.: 687-401

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis;

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said first elongation property is approximately 2.5% elongation beyond a normal state of said sling material when said sling material is subject to a tension of approximately 5 lbs.

15. (Amended) A sling for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said second elongation property is approximately 65% elongation beyond a normal state of said sling material when said sling material is subject to a tension of approximately 5 lbs.

16. (Amended) A sling for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and a second elongation property along said latitudinal axis,

USSN: 09/939,098

DRAFT AMENDMENT

Docket No.: 687-401

said first and second elongation property being different from each other,
said material is coated with a substance that enhances biocompatibility, and
wherein said first elongation property is approximately 10.5% elongation beyond a normal
state of said sling material when said sling material is subject to a tension of approximately 5
lbs.

A 11
17. (Amended) A sling for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to
prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a
latitudinal axis;

wherein said material has a first elongation property along said longitudinal axis, and
a second elongation property along said latitudinal axis,

said first and second elongation property being different from each other,

said material is coated with a substance that enhances biocompatibility, and

wherein said second elongation property is approximately 25% elongation beyond a
normal state of said sling material when said sling material is subject to a tension of
approximately 5 lbs.

Please cancel claim 26 without prejudice.

A 12
27. (Amended) A sling for insertion into a patient comprising:

a surgical sling adapted to support the urethra in its normal anatomic position and to
prevent abnormal urethral descent under intraabdominal pressure;

said surgical sling comprising a length of material having a longitudinal axis, and a
latitudinal axis;

USSN: 09/939,098

DRAFT AMENDMENT

Docket No.: 687-401

wherein said sling comprises a plurality of regions along its longitudinal axis and wherein each region contains differing elongation properties from an immediately adjacent region, and

wherein said sling material has a coated central region having an increased longitudinal elongation property and a somewhat decreased latitudinal elongation property as compared to elongation properties of said central region in a normal state.

A13
45. (Added) A sling according to claim 10 wherein the pores of the polypropylene material in the central region remain open and clear of silicone.

46. (Added) A sling according to claim 10 wherein said polypropylene comprises non-knitted polypropylene fibers.

47. (Added) A sling according to claim 46 wherein said non-knitted polypropylene fibers are multidirectional.

Please cancel claims 18-25 and 30-38 without prejudice to applicant's right to seek them in a divisional application.

A version marked up to show changes made to the claims relative to the previous version of the claims is attached.